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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,521

02/13/2007

Villoo Morawala Patell

20049.2USWO

2910

52835

7590

02/19/2010

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EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

02/19/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,521	<b>Applicant(s)</b> PATELL ET AL.	
	<b>Examiner</b> MICHELE FLOOD	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Acknowledgment is made of the receipt and entry of the preliminary amendment filed on February 15, 2006 with the addition of newly submitted Claims 20 and 21.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 3 and 5, drawn to a method for treating a disease selected from the group comprising cardiovascular disease, diabetes, degenerative neurological diseases, cancer, age related diseases like amyloidosis, acute pancreatitis, arthritis, atherosclerosis, cancer, heart disease, inflammatory bowel disease, myocardial infarction, senile dementia, retinal degeneration and senile cataract in a mammal, which comprises administering to the said mammal an effective non-toxic amount of at least an extract from *Terminalia arjuna* selected from those as defined in Tables 1 -24.

Group II, claims 2, 4 and 20, drawn to a method for treating infectious diseases in a mammal, which comprises administering to the said mammal an effective non-toxic amount of at least an extract from *Terminalia arjuna* selected from those as defined in Tables 1 – 24.

Group III, claims 6-10, and 21 drawn to a pharmaceutical formulation for use in the treatment of a disease selected from the group consisting of cardiovascular disease, diabetes, degenerative neurological diseases, cancer, age related diseases like amyloidosis, acute pancreatitis, arthritis, atherosclerosis, cancer, heart disease, inflammatory bowel disease, myocardial infarction, senile dementia, retinal degeneration and senile cataract, comprising at least one extract isolated from *Terminalia arjuna*, and selected from those listed in Tables 1-24 in admixture with a pharmaceutically acceptable carrier.

Art Unit: 1655

Group IV, claim 11, drawn to a method for the preparation of a pharmaceutical formulation comprising bringing into association at least an extract of the invention, and a pharmaceutically acceptable carrier therefore.

Group V, claims 12-15, drawn to an extract/comestible comprising at least an extract from *Terminalia arjuna* selected from the group consisting of the extracts having the HPLC and/or MS characteristics shown in Tables 1-24. The inventions are distinct, each from the other because of the following reasons:

Claims 16-19, drawn to non-statutory subject matter.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. Embodiments wherein a method for treating a disease is a disease selected from a member comprising the Markush group recited in Claim 1 and comprises administering an extract of *Terminalia arjuna* selected from those as defined in Tables 1-24; and the *Terminalia arjuna* extract is selected from the group consisting of AV016BaDi(65)04(100), AV016BaDi(28)04(20), AV016BaSu(65)09(100), AV016BaSu(65)01 (100), AV016BaSu(65)01 (100)g, AV016BaSu(65)01 (100)ng, AV016BaSu(65)04(100), AV016BaSu(65)06(100),

AV016BaSu(105)08(100), AV016FrDi(65)04(100) and  
AV016FrSu(105)08(100), or a combination of two or more thereof.

2. Embodiments wherein a method for treating an infectious diseases comprises administering an extract of *Terminalia arjuna* selected from those as defined in Tables 1-24; and the *Terminalia arjuna* extract is selected from the group consisting of AV016BaSu(65)09(100), AV016BaSu(65)01 (100), AV016BaSu(65)04(100), AV016BaSu(65)06(100), AV016BaSu(105)08(100), AV016FrDi(65)04(100) and V016FrSu(105)08(100), or a combination of two or more thereof.
3. Embodiments wherein a pharmaceutical formulation for treating a disease is a disease selected from a member comprising the Markush group recited in Claim 6 and comprises an extract of *Terminalia arjuna* selected from those as defined in Tables 1-24 in admixture with a pharmaceutically acceptable carrier; and wherein the *Terminalia arjuna* extract is selected from the group consisting of AV016BaDi(65)04(100), AV016BaDi(28)04(20), AV016BaSu(65)09(100), AV016BaSu(65)01 (100), AV016BaSu(65)01 (100)g, AV016BaSu(65)01 (100)ng, AV016BaSu(65)04(100), AV016BaSu(65)06(100),

Art Unit: 1655

AV016BaSu(105)08(100), AV016FrDi(65)04(100) and  
AV016FrSu(105)08(100), or a combination of two or more thereof.

4. Embodiments wherein a pharmaceutical formulation for treating any infectious disease comprises an extract of *Terminalia arjuna* selected from those as defined in Tables 1-24 in admixture with a pharmaceutically acceptable carrier; and comprises at least one *Terminalia arjuna* extract selected from the group consisting of AV016BaSu(65)09(100), AV016BaSu(65)01 (100), AV016BaSu(65)04(100), AV016BaSu(65)06(100), AV016BaSu(105)08(100), AV016FrDi(65)04(100) and AV016FrSu(105)08(100), or a combination of two or more thereof.
5. Embodiments wherein an extract from *Terminalia arjuna* is selected from the group consisting of the extracts having the HPLC and/or MS characteristics shown in Tables 1-24.
6. Embodiments wherein a comestible comprising at least an extract from *Terminalia arjuna* is selected from the group consisting of the extracts having the HPLC and/or MS characteristics shown in Tables 1-24.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

Art Unit: 1655

must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

In the instant case, Applicant is required to elect a single method of treatment, specifically naming either a method of treating a single disease as recited in Claim 1 or a method of treating an infectious disease in a mammal as recited in Claim 2, specifically stating and enumerating a single disclosed species of *Terminalia arjuna* as defined in Tables 1-24 and as recited in the Markush group recited in either of Claims 3 or 4. In addition, Applicant is required to elect a single pharmaceutical formulation or a single comestible, specifically stating and enumerating a single disclosed species of *Terminalia arjuna* as defined in Tables 1-24 and as recited in the Markush group recited in either of Claim 8 or disease condition as recited in the Markush group of Claim 14 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: No claims are generic.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE FLOOD whose telephone number is (571)272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood  
Primary Examiner  
Art Unit 1655

MCF  
February 5, 2010

/Michele Flood/  
Primary Examiner, Art Unit 1655